REMARKS

In the Final Office Action, Paper No. 14, received in the above-referenced application, pending claims 33-52 were rejected. In response thereto, claims 33 and 52 have been amended herein. As a result of this Amendment, claims 33-52 remain pending for the Examiner's consideration. No new matter has been added by this amendment. Reexamination and reconsideration of the application, as amended, are requested.

35 U.S.C. § 102(b) Rejections Addressed

1. Claims 33-52 are rejected under 35 U.S.C. § 102(b) as being anticipated by Holm et al. The Examiner points to Figures 1-3 and the Example to support this rejection. This rejection is respectfully traversed.

Independent claim 33 is directed to a system for the production of autologous thrombin comprising at least a first chamber for containing a portion of an inactivate (i.e., anticoagulated) blood component isolated by centrifugation of a blood sample in a reservoir. More specifically, claim 33 as amended herein recites a system for the production of autologous thrombin, comprising:

> (1) a centrifuge including a blood reservoir for receiving and separating an autologous anticoagulated blood sample having multiple inactive blood components; and
> (2) a dispenser disposed outside of the centrifuge and the blood reservoir and having at least a first collection chamber for receiving said at least one of said inactive blood components and a second collection chamber for receiving a second portion of the inactive component, wherein said first collection chamber activates the first portion of the inactive blood component and stores the resulting coagulated blood component comprising a clot and autologous thrombin.

Claim 52 has been similarly amended. Claims 33 and 52 as amended herein contain elements that are not taught in the cited art and therefore are clearly distinguished over the cited art. More specifically, the claims recite that the dispenser (including the first and second chambers) is not part of the centrifuge or the blood reservoir, nor is the dispenser or the first or second chambers ever used in the centrifuge for further processing of the anticoagulated blood component. Rather, is positioned outside of the centrifuge and reservoir for receiving and activating a first portion of the anticoagulated blood component, and the second chamber is also positioned outside of the centrifuge and reservoir for receiving a second portion of the anticoagulated blood component.

In contrast, Holm describes a multichambered device which is inserted into a centrifuge for separating plasma from blood. As described in column 9, lines 3-17, the Holm device comprises a first annular chamber 70 defined by a cylindrical outer wall 72, and a second chamber 75 defined by the same cylindrical outer wall 72 as the first chamber 70. Accordingly, all of the chambers are part of the Holm multichambered device, and therefore all of the chambers are placed within the centrifuge. Further, Holm does not teach or even

suggest a device comprising additional chamber disposed outside of the centrifuge or multichambered device for receiving a second portion of the separated blood component.

Since Holm does not teach or suggest a dispenser comprising a first chamber for receiving a first portion of the separated blood component and a second chamber for receiving a second portion of the blood component, Holm does not teach every element of claims 33-52 and therefore cannot anticipate claims 33-52. persuasive

2. Claims 33-52 are rejected under 35 U.S.C. § 102(b) as being anticipated by Antanavich et al. The Office Action pointed to the claims of Antanavich et al. for support of this rejection. This rejection is respectfully traversed.

As stated above, according to amended claims 33 and 52, the dispenser and therefore the chambers are not part of the centrifuge, nor are the chambers ever used in the centrifuge for further processing of the inactivated blood component.

In contrast, Antanavich discloses an apparatus for producing a platelet-rich plasma concentrate, which can then be combined with calcium (and optionally with bovine or human thrombin). The apparatus comprises a first chamber for separating plasma and platelets from whole blood, and a second chamber in fluid communication with the first chamber and containing a concentrator for concentrating the platelet rich plasma. The first and second chambers are part of the same device that is placed within a centrifuge (see column 12, lines 40-52 and column 13, lines 39-44). Further, Antanavich does not teach or even suggest an embodiment a device comprising additional chamber disposed outside of the centrifuge or device for receiving a second portion of the separated blood component.

Accordingly, Antanavich does not teach every element of claims 33-52, and therefore the Antanavich cannot anticipate claims 33-52 of the present case. persuasive

3. Claims 33-52 are rejected under 35 U.S.C. § 102(b) as being anticipated by Morse et al. (WO 91/09573). This rejection is respectfully traversed.

As stated above, according to claims 33 and 52 as amended herein, the chamber is not part of the centrifuge, nor is the chamber ever used in the centrifuge for further processing of the inactivated blood component.

In contrast, Morse teaches a system for collecting a blood coagulation factor (fibrinogen and Factor XIII). The system has a first container (i.e., a blood reservoir) for receiving and separating whole blood into plasma by centrifugation, and a second container for receiving a majority of the plasma. The second container contains an agent to effect

precipitation of the blood coagulation factor. Centrifugation of the second container separates the precipitated coagulation factor from the plasma. However, Morse does not teach or suggest an additional container for receiving a portion of the separated plasma. Thus, Morse does not disclose a system for producing autologous thrombin comprising a dispenser for receiving a separated blood component, wherein the dispenser comprises a first collection chamber for receiving a first portion of the blood component and a second collection chamber for receiving a second portion of the separated blood component. Accordingly, Morse does not teach every element of claims 33-52, and therefore the Morse does not anticipate claims 33-52 of the present case. not persuasive

CONCLUSIONS

It is believed that all claims now pending in this patent application, as amended and described above, are now allowable. Therefore, it is respectfully requested that the Examiner reconsider his rejections and to grant an early allowance. If any questions or issues remain to be resolved, the Examiner is requested to contact the undersigned at the telephone number listed below. No fees are believed to be required for filing this Amendment and Remarks. However, should any fee be required, please charge Deposit Account No. 50-1123.

Respectfully submitted,

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Date

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COMPLETE SET OF PENDING CLAIMS

33. (Previously added and presently amended) A system for the production of autologous thrombin, comprising:

a centrifuge including a blood reservoir for receiving and separating an autologous anticoagulated blood sample having multiple inactive blood components; and

means for removing at least one of said inactive blood components from said centrifuge upon separation~~; and~~ to a dispenser, said dispenser being disposed outside of said centrifuge and said blood reservoir and having at least ~~two collection chambers~~ a first collection chamber for receiving a first portion of said ~~at least one of said~~ inactive blood ~~components~~ component and a second chamber for receiving and storing a second portion of said inactive blood component, wherein ~~a~~ said first collection chamber activates ~~a~~ said first portion of said inactive blood component and stores the resulting coagulated blood component comprising a clot and said autologous thrombin.

34. (Previously added) The system of claim 33, further comprising a filter for separating said autologous thrombin from said clot.

35. (Previously added) The system of claim 33, wherein said anticoagulated blood sample is separated into various inactive blood components comprising a red blood cell component, a white blood cell component, a platelet rich plasma component and a platelet poor plasma component.

36. (Previously added) The system of claim 35, wherein said inactive blood components contain sodium citrate.

37. (Previously added) The system of claim 36, wherein said first collection chamber contains a restoration agent and an activation agent.

38. (Previously added) The system of claim 37, wherein said restoration agent is a calcium salt.

39. (Previously added) The system of claim 38, wherein said calcium salt is calcium chloride, calcium gluconate, or calcium carbonate.

40. (Previously added) The system of claim 37, wherein said activation agent is glass wool, silica, aluminum, diatomaceous earth, kaolin, plastic, siliconized glass, or a chemical activator.

41. (Previously added) The system of claim 35, wherein said anticoagulated blood sample contains heparin.

42. (Previously added) The system of claim 41, wherein said first collection chamber contains a restoration agent and an activation agent.

43. (Previously added) The system of claim 42, wherein said restoration agent is an anti-heparin agent.

44. (Previously added) The system of claim 43, wherein said anti-heparin agent is heparinase or protamine.

45. (Previously added) The system of claim 42, wherein said activation agent is glass wool, silica, aluminum, diatomaceous earth, kaolin, plastic, siliconized glass, or a chemical activator.

46. (Previously added) The system of claim 33, wherein said inactive blood component is platelet rich plasma.

47. (Previously added) The system of claim 46, wherein said platelet rich plasma in said first collection chamber coagulates as a result of being activated and the coagulated platelet rich plasma is triturated thereby expressing said autologous thrombin.

48. (Previously added) The system of claim 33, wherein said inactive blood component is platelet poor plasma.

49. (Previously added) The system of claim 48, wherein said platelet poor plasma in said first collection chamber coagulates as a result of being activated and the coagulated platelet poor plasma is triturated thereby expressing said autologous thrombin.

50. (Previously added) The system of claim 34, wherein said filter is positioned within said first collection chamber and comprises glass wool which also serves as a contact activator.

51. (Previously added) The system of claim 34, wherein said filter is positioned outside of said first collection chamber and has a pore size that allows said autologous thrombin to pass through said filter but retains said clot and debris from said clot.

52. (Previously added and presently amended) A system of the production of autologous thrombin, comprising:

a centrifuge including a blood reservoir for receiving and separating an autologous anticoagulated blood sample having multiple inactive blood components;

a lumen for transferring at least of said one inactive blood component from said blood reservoir to a dispenser upon separation, said dispenser <u>being disposed outside of said centrifuge and said blood reservoir and</u> having at least ~~two collection chambers~~ <u>a first collection chamber for receiving a first portion of said inactive blood component and a second chamber for receiving and storing a second portion of said inactive blood component,</u>

wherein ~~a~~ said first collection chamber activates a first portion of said inactive blood component and stores the resulting coagulated blood component comprising a clot and said autologous thrombin; and

a filter for separating said autologous thrombin from said coagulated blood component.